REMARKS

The present application includes pending claims 1-27, all of which have been rejected. The Applicant respectfully submits that the claims define patentable subject matter.

Claims 1-5, 8-15, 17-21, and 23-27 stand rejected under 35 U.S.C. 102(e) as being anticipated by United States Patent Application Publication 2004/0249673 ("Smith"). Claims 6, 7, 16, 17, and 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Smith in view of United States Patent No. 6,233,476 ("Strommer"). The Applicant respectfully traverses these rejections at least for the following reasons:

I. Smith Does Not Anticipate Claims 1-5, 8-15, 17-21, And 23-27

The Applicant first turns to the rejection of claims 1-5, 8-15, 17-21, and 23-27 as being anticipated by Smith. "'A claim is anticipated only if **each and every element** as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.'" *See* Manual of Patent Examining Procedure (MPEP) at § 2131 (internal citation omitted). Further, "'[t]he identical invention must be shown in as complete detail as it is contained... in the claim.'" *See id.* (internal citation omitted).

Smith "relates generally to medical devices and techniques, and more particularly to integrated point-of-care systems and methods for providing medical care to a patient." *See* Smith at [0003]. Smith discloses a computing system 160 and a medical devices 700. *See id.* at Figures 5 and 7. Smith discloses an identification device 615 that is in communication with the computing system 160.

> The identification device 615 generates data based on the physical characteristics of persons and provides the data to the I/O interface 510. Some examples of the identification

> device are biometric devices such as a fingerprint recognition device, a voice recognition device, and a retinal scanner. These biometric devices enhance the audit trail and advantageously increase security of the computing system 160 to prevent unauthorized users.

Id. at [0063]. Thus, as shown above, the identification device 615, which may be a biometric device, is used to prevent unauthorized use of the computing system 160. Further, "the computing system 160 controls access to the computing system 160 and the medical devices 700 based on the identity of the person attempting to operate the computing system 160." *See id.* at [0078].

Smith, however, does not describe, teach, or suggest imaging systems. As shown below, while Smith discloses medical devices, none of the medical devices are imaging devices.

> FIG. 7 depicts a block diagram of **medical devices 700** in an exemplary implementation of the invention. The **medical devices 700 include medical care devices 710 and medical monitoring devices 730**. The medical care devices 700 **provide medical care to a patient**. The medical monitoring devices 730 **measure the physiological status of the patient**."

Id. at [0073] (emphasis added). Thus, Smith discloses that the medical devices are either "medical care devices" that provide "medical care to a patient," or "medical monitoring devices" that "measure the physiological status of the patient." Neither the medical care devices, nor the medical monitoring devices," however, are "imaging devices.

In particular, Smith details the nature of the medical care devices 710 and the medical monitoring devices 730 (collectively, the medical devices 700). With respect to medical care devices, Smith states the following:

> The medical care devices 710 include a **ventilator** 170, **intravenous pumps** 136, a **radiant heater** 131, a **defibrillator** 718, and **a food pump** 720. The ventilator 170 **controls the respiration of a patient** based on data (e.g., control instructions) received from the device interface 515 (FIG. 5). The intravenous pumps 136 **deliver solutions containing a medication into a patient's bloodstream under pressure at a regulated flow rate** based on data (e.g., control instructions) received from the device interface 515. The radiant heater 131 **warms the patient to a desired temperature.** The defibrillator 718 **delivers cardioverting or defibrillating energy to the patient** according to the facility-defined protocols and user authorization. The food pump 720 **delivers liquid nutrition to the patient's gastrointestinal tract.**

Id. at [0074] (emphasis added). None of the medical care devices described in Smith, however, are "imaging devices."

Next, Smith describes the medical monitoring devices as follows:

> The exemplary medical monitoring devices 730 include an **oxygen monitor** 732, a **carbon dioxide monitor** 734, a **glucose monitor** 736, a **temperature monitor** 738, an **invasive blood pressure monitor** 740, a **non-invasive blood pressure monitor** 742, a **heart monitor** (e.g. EKG) 744, a **weight monitor** 746, a **central venous pressure (CVP) monitor** 748, a **respiration monitor** 750, a **pulse monitor** 752, **fluid/air output monitor** 134-135, a **cerebrospinal fluid (CSF) pressure monitor** 756, and a **tissue compartment pressure monitor** 758. The fluid/air output monitors 134-135 are configured to **monitor output of air and body fluids such as urine, nasogastric suction, chest tube output, biliary secretions, abdominal drain output, or other fluids**. The weight monitor 746 is used to **verify weight-based dosing to prevent a wrong dosage of medication for a specific weight**. The CSF pressure monitor 756 **is attached to an intracranial or intraspinal pressure monitoring device**. The tissue compartment pressure monitor 758 **is attached to a probe or transduced tube (gastric tube, bladder catheter) to follow the intracompartmental pressure of various body cavities.**

Id. at [0075] (emphasis added). Similar to the medical care devices, Smith does not describe any of the medical monitoring devices as being image devices.

In order to anticipate a claim, the MPEP requires that "'[t]he identical invention must be shown in as complete detail as it is contained... in the claim.'" *See* MPEP at § 2131. As detailed above, Smith discloses two types of medical devices: (1) medical care devices, and (2) medical monitoring devices. Smith, however, does not describe, teach, or suggest that the medical care devices and/or the medical monitoring devices are "imaging devices." Thus, Smith does not describe, teach, or suggest, "an imaging device in electrical communication with [a] central processing unit;... wherein a user inputs a biometric identifier into [a] biometric authorization unit in order to enable use of the imaging system," as recited in claim 1 of the present application. At least for this reason, Smith does not anticipate claim 1, or any of the claims that depend from claim 1.

Similarly, Smith does not describe, teach, or suggest, "a medical imaging device; and a biometric authorization unit, wherein a user inputs a biometric identifier into said biometric authorization unit in order to use the medical imaging device," as recited in claim 10 of the present application. At least for this reason, Smith does not anticipate claim 10, or any of the claims that depend from claim 10.

Additionally, Smith does not describe, teach, or suggest, "enabling use of [a] medical imaging system when biometric data input at [a] biometric authorization unit matches stored biometric data," as recited in claim 19. At least for this reason, Smith does not anticipate claim 19, or any of the claims that depend from claim 19.

Further, Smith does not describe, teach, or suggest, "enabling use of... audio/video equipment when biometric data input after... registering matches... stored

biometric data," as recited in claim 24. At least for this reason, Smith does not anticipate claim 24, or any of the claims that depend from claim 24.

II. The Proposed Combination Does Not Render Claims 6, 7, 16, 17, And 22 Unpatentable

The Applicant next turns to the rejection of claims 6, 7, 16, 17, and 22 as being unpatentable over Smith in view of United States Patent No. 6,233,476 ("Strommer"). As discussed above, Smith does not describe, teach, or suggest, a user inputting a biometric identifier into a biometric authorization unit in order to enable use of an imaging system. Strommer, however, does not overcome this deficiency in Smith. Further, the Office Action has not identified a motivation or suggestion within Smith or Strommer that would lead a person having ordinary skill in the art to combine these references.

In order for a *prima facie* case of obviousness to be established, the Manual of Patent Examining Procedure (MPEP) states the following:

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the teaching. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must **both be found in the prior art, and not based on applicant's disclosure.**

See Manual of Patent Examining Procedure (MPEP) at § 2142, citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (emphasis added).

The law is well settled that "obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or

suggestion or incentive to do so." *ACS Hospital Systems, Inc. v. Montfiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929 (Fed. Cir. 1984). It is not permissible to pick and choose among the individual elements of assorted prior art references to re-create the claimed invention, but rather "some teaching or suggestion in the references to support their use in the particular claimed combination" is needed. *Symbol Technologies, Inc. v. Opticon, Inc.* 935 F.2d 1569, 1576, 19 USPQ2d 1241 (Fed. Cir. 1991).

Additionally, if a *prima facie* case of obviousness is not established, Applicant is under no obligation to submit evidence of nonobviousness.

> The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness.

See Manual of Patent Examining Procedure MPEP at § 2142.

A. The Proposed Combination Does Not Teach All The Claim Limitations

Smith "relates to positioning systems in general, and to methods and systems for positioning an item within a living tissue." *See* Strommer at column 1, lines 4-6. While Strommer discloses a "biometric unit," it is not used to enable use of an imaging system. For example, Strommer states the following:

> The biometric unit includes at least one of the devices in the list consisting of an image detection unit, a substance releasing unit and a biometric sampling unit.

See Strommer at column 3, lines 55-57. In fact, the biometric unit "is designed to perform an inner operation on the living tissue." *See id.* at column 13, lines 49-50. Additionally, Strommer discloses the following:

> The biometric unit can include a biomedical sensor, wherein the biometric unit provides detected biometric information to the controller and wherein the controller produces a plurality of records. Each of the records can thus include a portion of the biometric information and a respective portion of the detected magnetic field information. The controller can store the records in the storage unit.

See id. at column 3, lines 61-67.

While Strommer discloses a biometric unit that may be an image detection unit, a substance releasing unit, a biometric sampling unit, or one that provides detected biometric information to a controller that produces a plurality of records, Stommer does not teach, nor suggest, "an imaging device...," in which a "user inputs a biometric identifier into [a] biometric authorization unit in order to **enable use of the imaging system**," such as recited, for example, in claim 1. Overall, the proposed combination of Smith and Strommer does not teach, nor suggest, enabling use of an ultrasound probe, or various other medical imaging systems, based on biometric data. Thus, at least for this reason, the Applicant respectfully submits that claims 6, 7, 16, 17, and 22 should be in condition for allowance.

B. No Motivation Or Suggestion To Combine Identified

As noted above, "the teaching or suggestion to make the claimed combination and the reasonable expectation of success must **both be found in the prior art, and not based on applicant's disclosure.**" *See* Manual of Patent Examining Procedure (MPEP) at § 2142 (emphasis added). The Office Action, however, states the following:

> However, an imaging system wherein the imaging device is an ultrasound probe and the imaging system is an ultrasound imaging system, wherein the imaging system is a medical

> imaging system... is considered conventional in the art as evidenced by the teachings of Strommer et al in Figure 5.
>
> Based on the above observations, for a person of ordinary skill in the art, modifying the system disclosed by Smith, with the above discussed enhancements would have been considered obvious because such modifications would have enhanced the capabilities of the system, resulting in a safer operating environment.

See February 8, 2006 Office Action at page 8. As noted above, the Office Action does not cite anything from the cited references or the prior art as support for its assertion regarding "modifying" Smith.

The Applicant respectfully submits, however, that there is nothing in **either reference** that would suggest enabling use of an imaging system through biometric data. Though the Office Action speculates that one might obtain a proposed benefit from the proposed combination ("enhanced capabilities, resulting in a safer operating environment), neither Smith nor Strommer identifies such limited capabilities of an imaging system that need to be solved, much less suggests how one might solve it. Such speculation is, moreover, no substitute for a suggestion that simply is not present in the cited references. *See In re Lee*, 277 F.3d 1338, 1344 (Fed. Cir. 2002).

Federal Circuit "case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references." *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999). The "examiner can satisfy the burden of showing obviousness of the combination 'only by showing some **objective** teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would

lead that individual to combine the relevant teaching reference.'" *See in re Lee , 277 F. 3d at 1343, citing In re Fitch,* 972 F. 2d 1260, 1265 (Fed. Cir. 1992) (emphasis added).

Merely citing portions of separate and distinct references that may or may not disclose an isolated claim element, however, is not a proper identification of a motivation to combine. The law requires that the Office Action show an **objective** teaching to support the assertions regarding motivation to combine the references.

In *In re Lee*, the Federal Circuit noted that the "Board rejected the need for 'any specific hint or suggestion in a particular reference' to support the combination of ... references," which was an "[o]mission of a relevant factor **required by precedent**" that was both "**legal error** and **arbitrary** agency action." *See id.* at1344, citing *Morot Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29 at 43 (1983) (emphasis added).

Subjective opinion of "common knowledge" or "common sense" regarding a motivation to combine is not enough to establish a *prima facie* case of obviousness. The Applicant respectfully submits that the motivation to combine Smith and Strommer identified in the Office Action is based on subjective knowledge and convenient assumptions gleaned from the Applicant's disclosure, instead of the references themselves (as is required by the Federal Circuit). Thus, at least for these reasons, the Applicant respectfully submits that the claims should be in condition for allowance.

III. Conclusion

The Applicant respectfully submits that the claims of the present application should be in condition for allowance at least for the reasons discussed above and request reconsideration of the claim rejections. If the Examiner has any questions or the

Applicants can be of any assistance, the Examiner is invited to contact the Applicant. The Commissioner is authorized to charge any necessary fees, or credit any overpayment to the Deposit Account of McAndrews, Held & Malloy, Account No. 07-0845.

Respectfully submitted,

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